Bisopro®

Bisoprolol Fumarate 2.5 & 5 mg

Presentation
Bisopro® 2.5: Each tablet contains Bisoprolol Fumarate USP 2.5 mg.
Bisopro® 5: Each tablet contains Bisoprolol Fumarate USP 5 mg.

Description
Bisoprolol is a beta1-selective (cardioselective) adrenoceptor blocking agent without significant membrane stabilizing activity or intrinsic sympathomimetic activity in its therapeutic dosage range.

Indications
Bisoprolol is indicated in the treatment of hypertension, angina and heart failure. It may be used alone or in combination with other antihypertensive agents.

Dosage and administration
The usual starting dose is 5 mg once daily. In some patients, 2.5 mg may be an appropriate starting dose. If the antihypertensive effect of 5 mg is inadequate, the dose may be increased to 10 mg and then, if necessary, to 20 mg once daily.

For heart failure
Initially 1.25 mg once daily (in the morning) for 1 week then, if well tolerated, increased to 2.5 mg once daily for 1 week, then 3.75 mg once daily for 1 week, then 5 mg once daily for 4 weeks, then 7.5 mg once daily for 4 weeks, then 10 mg once daily; max. 10 mg daily.

Use in Pregnancy and Lactation
Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. Bisoprolol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Nursing Mothers:
Small amounts of bisoprolol fumarate (< 2% of the dose) have been detected in the milk of lactating rats. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk caution should be exercised when bisoprolol fumarate is administered to nursing women.

Side-effects
Diarrhoea, dizziness, drowsiness, fatigue, headache, lightheadedness, nausea, sleeplessness, unusual tiredness, weakness, Severe allergic reactions (rash, hives, itching, difficulty breathing, tightness in the chest, swelling of the mouth, face, lips, or tongue), chest pain, difficulty breathing, lightheadedness or dizziness when rising from a lying or sitting position, very slow heartbeat.

Precaution
Impaired Renal or Hepatic Function.

Contraindication
Bisoprolol is contraindicated in patients with cardiogenic shock, overt cardiac failure, second or third degree AV block and marked sinus bradycardia.

Drug interactions
Bisoprolol should not be combined with other beta-blocking agents. Patients receiving catecholamine-depleting drugs, should be closely monitored, because the added beta-adrenergic blocking action of Bisoprolol may produce excessive reduction of sympathetic activity.
In patients receiving concurrent therapy with clonidine, if therapy is to be discontinued, it is suggested that Bisoprolol be discontinued for several days before the withdrawal of clonidine. Bisoprolol should be used with care when myocardial depressants or inhibitors of AV conduction, such as certain calcium antagonists or antiarrhythmic agents are used concurrently.
Concomitant use with digitalis glycosides can increase the risk of bradycardia.Concurrent use of rifampin increases the metabolic clearance of Bisoprolol, resulting in a shortened elimination half-life of Bisoprolol. However, initial dose modification is generally not necessary.

Overdosage
The most common signs expected with overdosage of a beta-blocker are bradycardia, hypotension, congestive heart failure, bronchospasm, and hypoglycemia. To date, a few cases of overdose (maximum: 2000 mg) with bisoprolol have been reported. Bradycardia and/or hypotension were noted. Sympathomimetic agents were given in some cases, and all patients recovered. In general, if overdose occurs, bisoprolol therapy should be stopped and supportive and symptomatic treatment should be provided. Limited data suggest that bisoprolol fumarate is not dialyzable. Based on the expected pharmacologic actions and recommendations for other beta-blockers, the following general measures should be considered when clinically warranted.

Storage
Do not store above 30^0 C. Keep away from light and out of the reach of children.

Commercial Pack
Bisopro®2.5: Each commercial box contains 5 blister strips of 10 tablets.
Bisopro® 5: Each commercial box contains 3 blister strips of 10 tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh

V.N.02